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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/883,842	06/18/2001	Stanley Stein	601-1-097 N	9975
23565	7590	09/22/2004	EXAMINER	
KLAUBER & JACKSON 411 HACKENSACK AVENUE HACKENSACK, NJ 07601			FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/883,842	<b>Applicant(s)</b> STEIN ET AL.	
	<b>Examiner</b> Blessing M. Fubara	<b>Art Unit</b> 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4-34 and 37-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5,6,13-19,25,33,37,38,40 and 43-51 is/are rejected.
- 7) ☒ Claim(s) 4,7-12,20-24,26-32,34,39,41 and 42 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>04/23/04 &amp; 4/30/04</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Examiner acknowledges receipt of request for extension of time and notice of appeal filed 10/20/03; amendment, remarks and request for continued examination under 1.114 filed 03/24/04; and IDS filed 04/30/04. Claims 1, 4-34 and new claims 37-51 are pending.

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 03/24/04 has been entered.

#### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 5, 6, 13-19, 25 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Trinh et al. (US 5,540,853).

Trinh discloses compositions that have the intended uses as personal care compositions that are normally rinsed off (column 6, lines 31-33) and hair care and topical skin care compositions that are not normally rinsed off or removed (column 30, lines 1 and 2). These compositions are emulsions comprising surfactants/detergents (abstract), optional suspending agents (column 16, line 2) and optional thickeners (column 17, line 14). The thickeners are

Art Unit: 1615

nonionic, anionic or cationic and the anionic polymers include cross-linked polymers that typically contain one or more monomers derived from acrylic acids and substituted acrylic acids (column 17, lines 15-67). When the topical skin-care composition is a pharmaceutical composition, it can contain pharmaceutical actives such as antifungal and antiviral drugs (column 41, lines 40-42).

Claim 1 is a broad composition that comprises a matrix and the matrix comprises an emulsion and the emulsion contains at least one therapeutic agent and at least one cross-linked polymer, where the therapeutic agent and the polymer are in the aqueous phase. An emulsion is understood by the person of ordinary skill to contain oil and water phases. A "matrix capable of delivering at least one therapeutic agent to a bodily compartment under controlled release conditions" as recited in generic claim 1 is a property of the composition and is not accorded any patentable weight. Claims 15 and 16 are directed to the inherent property of the composition.

On the basis on the above description of the prior art and discussion of the claims, Trinh meets the limitations of the claims.

4. Claims 37, 38, 40 and 43-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Yanaki et al. (US 5,538,728).

Yanaki discloses hydrogel composition (column 7, lines 21-25, 62-65; column 8, lines 3-11) that contains polysaccharide (column 3, lines 24-26), cross-linked polymer (column 3, lines 52-65), polyethylene glycol (column 11, line 2; column 13, line 39), pharmaceuticals such as antibiotics (column 12, lines 20-42); the composition can be an emulsion (column 28, line 22); the composition can be administered rectally (column 9, line 40); column 10, line 16). The

Art Unit: 1615

release order recited in claim 45 is an inherent property of the composition. Yanaki meets the limitations of the claims.

**Response to Applicants' Remarks on Wallace et al. (US 6,312,725) and Grinstaff et al. (US 5,498,421).**

The claims are amended to recite emulsion. Applicants' argument is thus persuasive that there is no teaching of emulsion in Wallace and Grinstaff. The rejection is not maintained and the applicants' argument is not further addressed in light of the new rejections.

The request to add an inventor and the revocation of power of attorney has not been received. Please advice.

5. Claims 4, 7-12, 20-24, 26-32, 34, 39, 41 and 42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Tech. Center 1600

